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(s) Saranel Salinas
Saranel Salinas

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Dubin et al.	Atty. Docket:	ORT-1601
Serial No.:	10/090,215	Art Unit:	1647
Filed:	March 4, 2002	Examiner:	Jon McClelland Lockard
For:	DNA ENCODING HUMAN VANILLOID RECEPTOR VR3	Confirmation No.:	5197

Mail Stop Appeal Brief--Patents
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APPELLANT'S BRIEF UNDER 37 C.F.R. § 41.37

Sir:

Further to the Notice Of Appeal filed October 5, 2005, Appellant submits the present brief in support of the appeal. A separate paper submitting payment of the required fee set forth at 37 C.F.R. § 41.20(b)(2) and the fee for a two-month extension of time accompanies this brief. If the accompanying payment is insufficient or if any other fees are due in connection with the filing of this brief, please charge any necessary fees to Deposit Account No. 10-0750.

Provided below are the items required by 37 C.F.R. § 41.37(c)(1) in separate sections.

I. Real Party in Interest

The real party in interest in this appeal is Ortho-McNeil Pharmaceutical, Inc. (as reflected in the assignment from the inventors of rights pertaining to the above-captioned application officially recorded on May 8, 2000, at Reel 010794, Frame 0753), which is a subsidiary of Johnson & Johnson.

II. Related Appeals and Interferences

There are no other prior or pending appeals, judicial proceedings, or interferences known to Appellant, the undersigned legal representative of Appellant, or the above-identified assignee that would directly affect, be directly affected by, or having a bearing on the Board's decision in the present appeal.

III. Status of Claims

There are 23 total claims in the application. Claims 11 and 23 have been rejected and are on appeal. Claims 1-10 and 12-22 have been canceled.

IV. Status of Amendments

The claims on appeal stand as presented in the Amendment And Reply To Office Action filed March 23, 2005. The final Office Action rejected these claims. Thereafter, a Reply To Final Office Action, which did not contain any amendment but provided new evidence in Exhibit A of the reply, was filed on October 5, 2005. As reflected in the Advisory Action dated December 22, 2005, the Examiner refused entry of the new evidence, which is therefore not relied on or referred to in this appeal.

V. Summary of Claimed Subject Matter

The invention defined by independent claim 11 is directed to an isolated protein comprising the amino acid sequence of SEQ.ID.NO.:12, which is an isoform of the human vanilloid receptor 3 (hVR3). See specification, e.g., page 7, line 26, through page 8, line 1. In the embodiment defined by claim 23, the protein consists of the amino acid sequence of SEQ.ID.NO.:12, which is the coding sequence for human VR3A+B+. See specification, e.g., page 5, lines 5-6, and Figure 8.

VI. Grounds of Rejection to be Reviewed on Appeal

One issue in the present appeal is whether the Examiner's final rejection of claims 11 and 23 under 35 U.S.C. § 101, as not being supported by either a specific and substantial asserted utility or a well-established utility, is in error. A related issue is whether the Examiner's final rejection of claims 11 and 23 under 35 U.S.C. § 112, first paragraph, for the same reason, is in error. The grounds for each rejection being the same, the present appeal turns on the question of whether claims 11 and 23 are supported by a specific and substantial asserted utility that is credible.

VII. Argument

Claims 11 and 23 satisfy the utility requirement of Section 101 as well as the how-to-use prong of the enablement requirement of Section 112, for the claimed subject matter is supported by a specific, substantial, and credible utility.

The Claims Meet the Utility Requirement of 35 U.S.C. § 101

Even though M.P.E.P. § 2107.02(III)(B) cautions against starting with a presumption that an asserted utility is *per se* incredible and then proceeding to base a Section 101 rejection on that presumption, the Examiner essentially did as much. In initially rejecting claims 11 and 23 as lacking utility, the Examiner asserted that "[n]ovel biological molecules lack an established utility and must undergo extensive experimentation to determine an appropriate specific, substantial, and credible utility" (Office Action mailed December 23, 2004, item 9 on page 3). There is no legal precedent, however, setting forth a *per se* rule that novel biological molecules must undergo extensive experimentation to establish utility. Instead, in determining whether the utility requirement has been met, the proper presumption is that Appellant's statement of utility is correct. See, e.g., In re Langer, 503 F.2d 1380, 183 U.S.P.Q. 288 (CCPA 1965).

Thus, the initial burden is not on an applicant to prove utility, but on the USPTO to provide evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility. See, e.g., In re Brana, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). Here, the Examiner has failed to establish a *prima facie* case of lack of utility.

The Examiner erred in the Section 101 analysis not only in starting with an assertion of incredible utility, but also in failing to properly recognize Appellant's statements of utility. In item 12 on page 5 of the Office Action dated December 23, 2004, and again at page 5 of the final Office Action dated June 6, 2004, the Examiner

contended that the specification identifies "neither . . . the biological functions of the claimed protein, nor any diseases that are associated with the claimed molecules." To the contrary, however, the specification indicates that the claimed protein may be used to identify modulators of the VR3 receptor, which should have utility as therapeutic agents in treating certain medical conditions or diseases, such as pain (see specification, page 3). Accordingly, a real-world utility specific to the claimed polypeptide has been identified.

Similarly, the specification does identify biological functions of the claimed protein. For example, the specification provides evidence of several biological properties of hVR3 and its associated protein, including experimental results reflecting that all three isoforms of VR3, including the VR3A+B+ isoform encompassed by the claims on appeal, function to enhance heat-induced response (see, e.g., Fig. 10 and its description; Example 5). Thus, the activities and functions are not purely conjectural or based solely on the protein being identified as a member of the TRP vanilloid (TRPV) subfamily. In fact, the Examiner has apparently recognized as much, considering the acknowledgment of Appellant's "*showing* of increased responsiveness to heat" (page 4 of each of the above-cited Office Actions, emphasis added).

Appellant not only has provided evidence in the specification reflecting that the claimed protein mediates responsiveness to a pain stimulus such as heat, but also has established the sequence homology of the claimed protein to known members of the TRPV subfamily. As apparent from the art citations at page 2 of the specification, the

literature reflects that other members of the subfamily appear to be involved in the sensation of pain-producing heat (see specification, page 2). Thus, it is not surprising that, faced with the totality of such evidence, the Examiner resorted to a presumption of incredible utility.

In item 14 at pages 5-6 of the Office Action of December 23, 2004, the Examiner did cite art, but it was merely in reference to the argument that the various members of the TRPV subfamily have different properties or functions. That different members of the TRPV subfamily have different properties or functions (as noted in the specification) is of little import, however, since it flows from the fact that they are not identical. Consequently, the fact that the claimed protein does not have entirely the same set of properties (e.g., membrane conductance, etc.) as other members of the TRPV subfamily does not negate utility as urged by the Examiner, for even one property imparting a specific, substantial utility is sufficient. Simply because the distinct protein of the invention does not function identically in all respects as other members of the TRPV subfamily does not establish that artisans would doubt that the protein would have the asserted utility, especially when the totality of the evidence (including that demonstrating the impact on responsiveness to heat) is properly considered.

The Claims Likewise Meet the Utility Prong of the Enablement Requirement of 35 U.S.C. § 112

As established above, the Examiner has failed to carry the USPTO's burden of making a *prima facie* showing that the claimed invention is not supported by a disclosure of utility that is specific, substantial, and credible. Rather, the preponderance of the evidence would lead a person of ordinary skill in the art to conclude that the stated utility is likely true. Indeed, the previous Examiner responsible for this application did not doubt the asserted utility, for that Examiner indicated that the claimed subject matter was allowable. Appellant submits that the present Examiner's decision is in error and therefore the claimed subject matter should once again be officially recognized as being allowable.

For the foregoing reasons, Appellant requests the Board to reverse the decision of the Examiner rejecting claims 11 and 23 under 35 U.S.C. § 101 and § 112.

Respectfully submitted,

Date: February 6, 2006

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Claims Appendix

Claims on appeal:

11. An isolated protein comprising the amino acid sequence set forth in SEQ.ID.NO.:12.

23. An isolated protein as defined in claim 11, wherein the protein consists of the amino acid sequence set forth in SEQ.ID.NO:12.

Evidence Appendix

This appeal does not rely on any evidence submitted pursuant to 37 C.F.R. § 1.130, 1.131, or 1.132 that has been entered by the Examiner.

Related Proceedings Appendix

None.